JUL 20 2011

5. 510(k) Summary (21 CFR 807.92)

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K110797

Submitter's name:	Christopher Relyea
Submitter's address:	160 West 71st Street, 18th Floor, New York, NY 10023, USA
Phone number:	646-526-7111
Fax number:	203-621-3198
Name of contact person:	Christopher Relyea
Date the summary was prepared:	02/23/2011

Device Name/Trade Name:	Communify PACS Viewer
Common Name:	Medical Image Workstation
Classification Name:	21 CFR 892.2050
Product Code	LLZ

Substantially equivalent to the devices are the following:

Manufacturer	Device	510(k)
Viztek, Inc.	Opal-RAD	K063337
RamSoft, Inc.	RamSoft PACS	KO31562
General Electric Medical Systems	Centricity PACS Plus	KO23557

Comparison to Predicate Devices

The similarity of Communify PACS Viewer with the predicate devices listed above is that they all are or contain PACS Viewer software systems. They can all process and display medical images from DICOM compliant modalities such as CR, CT, DX, MR, NM, PT, RF, US, XA, and others.

Most of the tools, features, and settings in the PACS Viewers are commonly available across Communify PACS Viewer and the predicate devices listed above. Each device, including Communify PACS Viewer, has its own slightly unique interface, but someone familiar with any of the devices should be able to use any other device without difficulty.

Conclusion

The Communify PACS Viewer meets its intended use and design specifications for a picture archiving and communications system viewer. It has the required capabilities relating to the transfer, display, and digital processing of medical images. It is our conclusion that Communify PACS Viewer is significantly comparable to the PACS Viewers within Opal-RAD, RamSoft PACS, and Centricity PACS Plus.

Device Description

The Communify PACS Viewer is an application which allows users to view, manipulate,

annotate, transmit to other facilities, print, and animate all manner of DICOM images and modalities. These modalities include, but are not limited to, CR, CT, DX, MR, NM, PT, RF, US, and XA.

The Communify PACS Viewer contains common image manipulation functions (such as zoom, pan, triangulation, and window/level) and common image labeling tools (including measurements tools, drawing tools, and annotation overlays). The annotation overlay displays all the important metadata (as configured by the user) for each displayed series study. Although annotation fields depend on the modality and the patient study, the Annotation Overlay Template Wizard provides a full list of annotation fields that the user can assign into the image display.

For easy access to tools and features, there are shortcut keys, toolbars, and right-click menus.

The Hanging Protocol editor of the Communify PACS Viewer configures the presentation layout of images on the screen when a study is loaded. This allows commonly used display formats and presets to be saved and easily accessed to allow for faster case study reviews.

Intended Use Statement

The Communify PACS Viewer is an image display software application that is intended for use by qualified physicians and other personnel for reading, diagnostic review, and analysis of digital images acquired from imaging devices such as CT, MR, CR, DX, MG, US, NM, PET, and other devices. The Communify PACS Viewer is a Picture Archiving and Communications System (PACS) viewer designed to be used to view Digital Imaging and Communications in Media (DICOM) and non-DICOM information and data.

The Communify PACS Viewer is an image display software application that accepts DICOM data from any OEM modality which supports DICOM standard imaging data; the system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, and perform quantitative measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Chris Relyca
CEO
Flying Squirrel Storage LLC
160 West 71st Street, 18th Floor
NEW YORK NY 10023

JUL 20 2011

Re: K110797
Trade/Device Name: Communify PACS Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 2, 2011
Received: July 7, 2011

Dear Mr. Relyca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K110797

Device Name: Communify PACS Viewer

Indications for Use:

The Communify PACS Viewer is a Picture Archiving and Communications System (PACS) viewer designed to be used to view Digital Imaging and Communications in Media (DICOM) and non-DICOM information and data. The Communify PACS Viewer is a software application that runs on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. Communify PACS Viewer is an image and display software that accepts DICOM data from any OEM modality which supports DICOM standard imaging data; the system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulations, create graphical representations of anatomical areas, and perform quantitative measurements.

Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

Prescription Use __X__ Over-The-Counter Use

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110797

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)